Individual Safety Report

3547389-3-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	60 yrs or ____ Date of birth: [redacted]	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(x) other: recovered

3. Date of event (mo/day/yr): 10/99

4. Date of this report (mo/day/yr): 05/18/00

5. Describe event or problem

Consumer report received via internet alleges that the use of an unspecified TYLENOL® acetaminophen product was associated with producing abnormal liver enzymes (LIVER FUNCTION TESTS ABNORMAL). According to consumer's Internet report, he has been using product "for years" and has "recently learned that it was killing me by producing abnormal liver enzymes." Addl info rec'd via telephone conversation with consumer on 5/24/00: Consumer reports using 4 to 6 Extra Strength TYLENOL per day for pain and 2 Extra Strength TYLENOL PM per night for sleep for at least 3 years. At a routine appt with his MD in 10/99, his liver enzymes were reportedly found to be elevated. Similar liver enzyme counts were seen on 2 subsequent visits with his MD. He also reports that his fibromyalgia pain got worse while using Extra Strength TYLENOL (AGGRAVATION REACTION). His MD reportedly ruled out hepatitis and attributed symptoms to use of products. Consumer reports discontinuing use of products as directed by his MD and symptoms subsequently resolved.

6. Relevant tests/laboratory data, including dates

10/99: consumer reports having "abnormal liver enzymes"

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

fibromyalgia, seasonal allergies, s/p quadruple bypass, consumer reports a doctor found liver damage due to an unspecified hepatitis virus prior to use of TYLENOL; allergic to aspirin, AMOXIL®, and other unspecified penicillin derivatives

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product
#2 Extra Strength TYLENOL PM product

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 2000-3000 mg/day, po	#1 "at least 3 years"
#2 2 pills, qhs, po	#2 "at least 3 years"

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 pain	#1 (X) Yes ( ) No ( ) N/A
#2 sleep	#2 (X) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1 unknown	#1 unknown	#1 ( ) Yes ( ) No (X) N/A
#2 unknown	#2 unknown	#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

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10. Concomitant medical products and therapy dates (exclude treatment of event)

unspecified heart medications

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(x) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
(x) other: Internet

4. Date received by manufacturer (mo/day/yr): 05/17/00

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day ( )15-day
( ) 10-day (X)periodic
(X) Initial ( )follow-up #

8. Adverse event term(s)

LIVER FUNC ABNO REACTION AGGRAV

9. Mfr. report number

1364863A

E. Initial reporter

1. Name, address & phone #

AUG - 9 2000

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes ( ) No		( ) Yes ( ) No ( ) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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